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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,620	08/10/2001	Shirley I. Micka	CI-0002	2935
34610	7590	10/07/2003	EXAMINER	
FLESHNER & KIM, LLP P.O. BOX 221200 CHANTILLY, VA 20153			MCKANE, ELIZABETH L	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/925,620

Applicant(s)

MIEKKA ET AL.

Examiner

Leigh McKane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40, 44-67 and 69-77 is/are rejected.
- 7) ☒ Claim(s) 41-43, 68 and 78-80 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 67, 11, 12
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

*Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 11-14, 33, 44-46, 54, 59, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kent (6,171,549).

3. Kent teaches a method for sterilizing sensitive biological materials containing viruses, bacteria, yeasts, molds, mycoplasmas, and/or parasites, wherein the materials are irradiated at ambient temperature with gamma radiation at a dose rate from about 0.1-3.0 kGy/hr for a period of time sufficient to sterilize the material. See Abstract. The biological materials may be diluted (with a solvent) prior to irradiation. Kent further discloses adding a stabilizer (ethanol) to the material prior to irradiation. See col.3, lines 3-6.

4. Claims 1-3, 5-7, 11-14, 24-31, 33-35, 39, 44-46, 54, and 59-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakai et al ("Microbiological Studies on Drugs and Their Raw Materials").

Sakai et al discloses lyophilizing an aqueous enzyme sample to a dry powder and then irradiating the sample at room temperature with gamma radiation at a dose rate of  $3.45 \times 10^4$  rad/hr (0.345 kGy/hr) for a time sufficient to sterilize the sample. Stabilizers such as glucose or L-cysteine may be added to the sample prior to irradiation. The sample is initially contaminated with bacteria.

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5. Claims 5, 9, 15-19, 24-31, 33, 47, 54 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Odland (U.S. Patent No. 5,989,498).

Odland teaches a method for sterilizing a biological material wherein a stabilizer (crosslinking agent) is first added to the material. Then the material is immersed in an organic solvent (ethanol) to inhibit calcification, after which the organic solvent is removed by rinsing (addition of solute) and then the material is irradiated with e-beam radiation at a rate (7800 Gy/min = 468 kGy/hr) and for a time sufficient to sterilize the material. See col.7, lines 39-68.

6. Claims 60-67 and 69-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson (U.S. Patent No. 5,730,933).

Peterson teaches a sterile biological material wherein the material is lyophilized, treated with a free-radical scavenger or antioxidant, stored in a vacuum with an inert gas, and irradiated with gamma radiation. See col.5, line 8 to col.6, line 18. The biological material may be a globulin or an enzyme. See col.3, lines 49-50.

7. Claims 2, 32-39, 40, 44, 45, 49, 54, 55, and are rejected under 35 U.S.C. 102(b) as being anticipated by Wieseahn et al (U.S. Patent No. 4,727,027).

Wieseahn et al teaches a method for sterilizing biological materials with UV radiation at a controlled rate and for a time sufficient to sterilize the material. See col.4, lines 20-40. A sensitizer and/or oxygen scavenger may be added to the material before irradiation and preferably the material is irradiated at a temperature below 60 °C, most preferably -10 to 30 °C. A stabilizer (heparin) is added to control any activated clotting factors (col.11, lines 31-33).

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8. Claims 2 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Ben-Hur et al (U.S. Patent No. 5,637,451).

Ben-Hur et al teaches a method for sterilizing biological materials with visible radiation at a controlled rate and for a time sufficient to sterilize the material. See col.3, lines 41-61. A sensitizer and/or oxygen scavenger may be added to the material before irradiation.

### *Claim Rejections - 35 USC § 103*

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 2, 5, 9-14, 32-36, 39, 44-46, and 48-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horowitz et al (U.S. Patent No. 5,981,163) in view of Kent.

Horowitz et al teaches the sterilization of biological materials, including blood products, wherein the material is treated with a sensitizer and a stabilizer mixture (antioxidant and free-radical scavenger) and irradiated with gamma radiation. Horowitz et al does not disclose controlling the dose rate. However, Kent, teaches that when sterilizing sensitive biological materials with gamma radiation, one should choose a low dose rate (0.1-3.0 kGy/hr). See Abstract. As this dose rate is disclosed by Kent to be effective in sterilizing without undue damage to the biological material, it would have been obvious to use in the method of Horowitz et al.

Horowitz et al discloses that the use of a stabilizer is combinable with many forms of radiation sterilization. Horowitz et al evidences "[n]on-limiting examples...UV...gamma-irradiation, x-rays, and visible light" (col.6, lines 46-54) and teaches that "'irradiation' is to be construed broadly to include any from of radiation conventionally used to inactivate cells...". Thus, it is deemed obvious to employ other types of radiation in the method Horowitz et al.

Horowitz et al discloses that it was known in the art to combine the treatment of a biological material with irradiation and a stabilizer mixture with a second virucidal treatment such as, treatment with an organic (lipid) solvent. See col.7, line 66 to col.8, line 8. Moreover, in col.6, lines 16-19, Horowitz et al teaches that it was known in the art to obtain plasma fractions by treating the blood for organic solvents such as ethanol and PEG to effect

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precipitation of a desired fraction. The obtained fraction is subsequently treated by the sterilization method of Horowitz et al.

13. Claims 4-8, 20-36, 39, 40, 44, 47, and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson in view of Kent.

Peterson teaches a method of sterilizing a biological material wherein the material is lyophilized, treated with a free-radical scavenger or antioxidant, stored in a vacuum with an inert gas at  $-70^{\circ}\text{C}$ , and irradiated with gamma radiation. See col.5, line 8 to col.6, line 18. Peterson discloses that an alternative to lyophilization is the use of drying agents (i.e. organic solvents). Suitable free-radical scavengers/antioxidants include propyl gallate and ascorbic acid. Although Peterson discloses a total dose of radiation, a particular dose rate is not taught. Kent, however, discloses that a low dose rate of about 0.1-3.0 kGy/hr is sufficient to achieve sterilization yet does not destroy sensitive materials such as blood and blood components like those treated by the method of Peterson. For this reason it would have been obvious to use the dose rate of Kent in the method of Peterson.

*Allowable Subject Matter*

14. Claims 41-43, 68, and 78-80 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter:  
The closest prior art, while teaching irradiation of sensitive biological materials, fails to teach or

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suggest: i) a mixture of stabilizers as claimed in claim 41; ii) a dipeptide stabilizer; iii) glassy or vitrified material; or iv) a ligand sensitizer.

*Conclusion*

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 703-305-3387. The examiner can normally be reached on Monday-Wednesday (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

  
**Leigh McKane**  
**Primary Examiner**  
**Art Unit 1744**

elm  
25 September 2003